REMARKS

Claims 1, 3-11, 13, 15-27, 29-31, 37, 40-47 and 56-68, as amended, are pending in this application for the Examiner's review and consideration. The independent claims 1, 37 and 60 have been amended to recite that the active agent is a hormone. Claims 1 and 37 have been amended to recite preferred embodiments, i.e., when the active agent is testosterone, the testosterone is the sole active agent and it is present in an amount of 1% or less by weight of the formulation. Claims 7 and 60 have been amended to replace the phrase "monoalkyl ether of diethylene ether" with the phrase "monoalkyl ether of diethylene glycol", support for which is found throughout the specification and claims, as indicated by the Examiner. Claim 60 has also been amended to correct the recitation of propylene glycol. Claims 8, 15, 26 and 43 have been amended to make it clear that the combination of estrogen and progestin are excluded. Claim 28 has been cancelled. Claim 13 has been amended to be consistent with claim 1 and claims 43 and 59 have been amended to be consistent with claim 37. Since no new matter has been introduced by any of these changes, they should all be entered at this time.

Claims 1, 5-7, 11, 13, 26, 37, 40-42, 46, 47, 56-58, 60-63 and 68 have been rejected under 35 U.S.C. 112, first paragraph, for allegedly failing to comply with the enablement requirement. In particular, the Examiner alleges that the specification, while being enabling for gel formulations for the transdermal or transmucosal administration of an androgen, estrogen or progestin, does not reasonably provide enablement for gel formulations for the transdermal or transmucosal administration of any active agent. Applicants respectfully disagree. It is respectfully submitted that the specification and the claims recite all the key ingredients of the presently claimed gel formulation. Therefore, the specification does enable a person of ordinary skill in the art to use the invention without undue experimentation. To facilitate the prosecution of this application, however, the claims have been amended to recite that the active agent is a hormone, support for which is provided by the disclosure and examples of estrogen, progestin and testosterone. Therefore, the rejection should be withdrawn.

Claims 1, 3-11, 13, 15-31, 37, 40-47 and 56-68 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite using "between about" in references to concentration ranges, "from about"... "to about" in reference to effective dosage amounts, and "to about" in reference to serum levels. Applicants respectfully disagree. As stated in MPEP 2173.05(b), "the fact that claim language, including terms of degree, may not be precise, does

not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph." *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). MPEP 2173.05(b) further states that "acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification." In particular, for "determining the range encompassed by the term 'about', one must consider the context of the term as it is used in the specification and claims of the application. Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd., 476 F.3d 1321, 1326, 81 USPQ2d 1427, 1432 (Fed. Cir. 2007). Moreover, in W.L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. Thus, the phrases recited in the present claims, i.e., "between about", "from about" ... "to about", and "to about" are specific and definite. Therefore, the rejection should be withdrawn.

Claims 7, 60, 66 and 68 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, the phrase "monoalkyl ether of diethylene ether" in claims 7 and 60 have been amended to "monoalkyl ether of diethylene glycol." Therefore, the rejection should be withdrawn.

Claims 28 and 43-45 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, claims 28 has been cancelled and claim 43 has been amended to be consistent with claim 37. Therefore, the rejection should be withdrawn.

Claim 59 has been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, claim 59 has been amended to be consistent with claim 37. Therefore, the rejection should be withdrawn.

Claims 1, 5-7, 11, 37, 40-42, 46, 47, 60 and 64 have been rejected under 35 U.S.C. 102(b) as allegedly being anticipated by International Patent Application Publication No. WO 2002/011768 to Carrara et al. (referred to hereafter as "Carrara").

Carrara relates to a pharmaceutical formulation with good cosmetic properties and low irritation potential for the systemic treatment of diverse diseases by transdermal or transmucosal route, comprising as permeation enhancers defined amounts of fatty alcohols such as lauryl alcohol, n-decanol and oleyl alcohol in a ternary vehicle composite consisting of ethanol, propylene glycol and water, and optionally also a monoalkylether of diethylene glycol. As acknowledged by the Examiner, Carrara discloses a composition comprising 1.25 wt% testosterone. In contrast, claims 1 and 37 as amended now recite and claim that when the active agent is testosterone, the testosterone is the sole active agent and it is present in an amount of 1% or less by weight of the formulation. As there is no teaching or suggestion in Carrara to modify the amount of testosterone to 1% or less by weight of the formulation, as presently claimed, Carrara does not teach or suggest the presently claimed invention. Therefore, the rejection should be withdrawn.

Claims 1, 3-8, 10, 11, 13, 15, 20, 22, 26, 28, 37, 40-43, 45-47, 56, 57, 60-62 and 68 have been rejected under 35 U.S.C. 102(a) as allegedly being anticipated by WO 02/22132 to Gray et al. (US Patent 7,030,104 is the English-language equivalent and is relied upon by the Examiner, referred to collectively as "Gray"), or under 35 U.S.C. 102(e) as allegedly being anticipated by US Patent No. 7,030,104 to Gray et al.

Claims 1, 37 and 60 now recite formulations that are not disclosed by Gray. As noted above, the claims are directed to formulations that contain at least one active agent of a hormone, provided when the active agent is estrogen, progestin is not present in the formulation in a therapeutically effective amount, and when the active agent is progestin, estrogen is not present in the formulation in a therapeutically effective amount and further provided that, when the active agent is testosterone, the testosterone is the sole active agent and it is present in an amount of 1% or less by weight of the formulation. Gray does not disclose any of these formulations so that the claims are not anticipated by Gray. Thus, the anticipation rejection should be withdrawn.

Claims 1, 3-11, 13, 15-20, 22, 26, 28, 29, 31, 37, 40-47, 56-63 and 65-68 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Gray et al. (WO 02/22132; US Patent 7,030,104 is the English-language equivalent and is relied upon herein), in view of US Patent No. 6,503,894 to Dudley et al. (referred to hereafter as "Dudley"), US Patent No. 5,955,455 to Labrie et al. (referred to hereafter as "Labrie") and US Patent No. 5, 397,771 to

Bechgaard et al. (referred to hereafter as "Bechgaard"). Also, claims 1, 3-8, 10, 11, 13, 15, 20-28, 37, 40-43, 45-47, 56, 57 and 60-62 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Gray in view of a journal article by Catherino et al. (J. Steroid Biochem. Molec. Biol., 1995, referred to hereinafter "Catherino") and Carrara.

As noted above, Gray does not teach the present claims so that the secondary references have been cited in an attempt to remedy the deficiencies of Gray. Applicants traverse these rejections.

Gray mentions a number of different formulations but he does have a few examples of formulations that include ethanol, propylene glycol and Transcutol, except that these are used for the combination of estrogen and progestin. Gray does not teach or recognize the criticality of the combination of components of the delivery vehicle that is used in the presently claimed formulations. Instead, Gray discloses that long chain fatty compounds are also useful as are compounds such as Solketal among others. None of these are included in the present claims, nor do they provide the desired results. For example, the present invention relates to formulations that are substantially free of malodorous long-chain fatty alcohols and long-chain fatty acids. Surprisingly, the formulation of the present invention can achieve sufficient absorption to result in an effective dosage of the selected active agent(s) circulating in serum without the inclusion of the long-chain fatty alcohols and the long-chain fatty acids that have been used to date. This in turn leads to greater patient compliance and greater effectiveness as the formulations are in fact well tolerated when administered.

In addition, the present application includes a number of examples of hormone gels and shows their effectiveness for treating a variety of conditions, such as for treating hypogonadism, female menopausal symptoms, female sexual dysfunction, hypoactive sexual desire disorder, and adrenal insufficiency, and wherein the administration of the formulation decreases the frequency of at least one clinical symptom of the hormonal disorder.

The various references that have been combined in the office action are not related and do not teach that they should be combined as suggested. In fact, each has their own formulations and reasons for such formulations. They also include additional permeation components of the types that are excluded from the present claims, e.g., fatty compounds, and others so that it is certainly not clear as to how a skilled artisan could come up with the present formulations except after undue testing. The office action itself cites these types of concerns which supports this

explanation. Furthermore, to come up with the present formulations, since there is no teaching to do so other than the present specification, one must selectively pick and choose from various combinations of ingredients using the present specification as a guide. Of course, rejections made in this manner are discouraged by the Court of Appeals for the Federal Circuit. Thus, the rejections based on combinations of unrelated references have been overcome and should be withdrawn.

Accordingly, it is believed that the entire application is now in condition for allowance, early notice of which would be appreciated. In the event that the Examiner does not agree that all claims are now allowable, a personal or telephonic interview is respectfully requested to discuss any remaining issues in an effort to expedite the eventual allowance of this application.

Respectfully submitted,

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